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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/469,717	12/21/99	NARCISO H	353532000710

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MORRISON AND FOERSTER LLP
755 PAGE MILL ROAD
PALO ALTO CA 94304-1018

EXAMINER	
DROESCH,K	
ART UNIT	**PAPER NUMBER**
3731	FF5

DATE MAILED: 11/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/469,717	NARCISO, HUGH L.	
	Examiner	Art Unit	
	Kristen L. Droesch	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 46-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 46-67 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

Some of the references listed in the PTO-1449 form were not considered since they were unavailable to the examiner. The examiner requests copies of these references.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 51, and 62-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 51 recites the limitation "said biocompatible material" in line 1 of claim 51. There is insufficient antecedent basis for this limitation in the claim. Claims 62-67 each recite the limitation "fastener of claim 61". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 46-59, and 61-67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The anastomosis device comprising a graft vessel, where the graft vessel is described as a thoracic artery or saphenous vein in line 7 of Column 5, of the specification, is directed to non-statutory subject matter because the claims positively recite a part of the human body. The examiner suggests replacing the existing phrases to

language such as -- where the tubular member is adapted to be connected to a graft vessel-- , -- the end margin of the tubular member is configured to be inserted into an end portion of a graft vessel-- , --the tubular member is adapted to be adhered to an end portion of a graft vessel-- and, --where the polymeric material is configured to be disposed upon an end margin of a free end of a graft vessel--.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 46, 49-55, 58-62, and 64-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Slepian (5,634,946). Slepian teaches of a device that can be used for sealing vessel anastomoses during coronary artery bypass surgery (Column 12, lines 9-12), comprising a tubular member made of a deformable material where the tubular member is transformable upon application of energy between a non-fluent state and a fluent state in which the tubular member is radially expandable (Column 10, lines 46-60). With respect to claims 49-51, and 62, Slepian teaches that the tubular member is formed of a biocompatible, bioerodable polymeric material (Column 7, lines 32-44, Column 8, lines 4-15). With respect to claim 52, Slepian teaches that the polymer can either be a homopolymer or a copolymer (Column 7, lines 46-49). With respect to claim 53, Slepian teaches that the polymeric material is polycaprolactone (Column 8, lines 16-46). With respect to claims 54 and 55, Slepian teaches that the tubular member has an adhesive

surface and an end portion of a graft vessel can be adhered to the tubular member (Column 12, lines 9-12, Column 12, lines 52-56, and Column 14, lines 40-46). With respect to claims 58-59, 64, and 65, Slepian teaches that the tubular member can be impregnated with anti-platelet, anti-thrombus, anti-inflammatory, and anti-proliferative compounds (Column 9, lines 25-43). With respect to claims 60 and 61, Slepian teaches that the tubular member is sized and dimensioned for receiving an end portion of a graft vessel, and that material is disposed upon an end margin of a free end of a graft vessel (Column 10, lines 46-49). It is inherent that when the tubular member is radially expanded, it is capable of forcing the graft vessel into sealing engagement with an inner wall of a target vessel. With respect to claims 66, and 67, Slepian teaches that the material can be applied to an inner wall of a graft vessel (Column 5, lines 28-34). It is inherent that the material could also be applied to an outer wall of a graft vessel.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash et al. (6,056,762). Slepian is explained as before. Slepian teaches that the initial pre-deployment design and size of the polymer sleeve will be dictated by the specific application based upon the final physical, physiological and pharmacological properties desired. (Column 12, lines 28-32). However, Slepian does not teach that the tubular member is pre-shaped to have at least a first bend along the length of the member or a portion of the tubular member extends at an angle between 30^0 and 90^0 relative to the longitudinal centerline. Nash et al. shows an

anastomosis system comprising a tubular member (22) with a first bend along the length of the member (Figure 3). Nash et al. also shows that a portion of the tubular member extends at an angle between 30^0 and 90^0 relative to the longitudinal centerline (Figure 3, and Column 6, lines 44-47). Nash et al. teaches that the angled configuration facilitates insertion into the target vessel (Column 6, lines 47-50). It would have been obvious to one with ordinary skill in the art at the time of the invention to use a tubular member with a first bend or portion of the tubular member extending at an angle between 30^0 and 90^0 relative to the longitudinal centerline as described by Nash et al. and apply it to the invention of Slepian in order to facilitate insertion into a target vessel.

8. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712). Slepian is as explained before. Slepian does not teach of including in the tubular member a chromophore or dye. Pathak teaches of forming polymeric materials *in vivo*, where the polymeric materials include a chromophore such as a dye or a pigment (Column 2, lines 54-59). Pathak teaches that the chromophore serves to absorb light produced by a light source and convert it to thermal energy, which acts to heat the polymer. It would have been obvious to one with ordinary skill in the art at the time of the invention to include a chromophore is the form of a dye, as taught by Pathak, in the tubular member of Slepian in order for the tubular member to be transformable by the application of light energy.

9. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Slepian is as explained before. Slepian does not teach that the material is selected from a group consisting of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes. Hubbell teaches of tissue contacting materials formed from polyethylene-

glycol (PEG) base hydrogels, acrylates, or acrylated urethanes (Column 5, line 15-23, and Column 27, lines 53-55). Hubbell teaches that acrylates permit rapid polymerization and gelation and can be polymerized by several initiating systems. Hubbell teaches that PEG is hydrophilic and water soluble and has excellent biocompatibility. It would have been obvious to one skilled in the art at the time of the invention to use this group of materials for the device of Slepian since this group of materials is rapidly transformable upon the application of energy between a non-fluent and a fluent state, is water soluble, and has excellent biocompatibility.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hubbell (5,573,934) also teaches of the use of PEG, acrylates and acrylated urethanes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L. Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Recla can be reached on 703-308-1382. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2708 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

kld
October 31, 2000

MICHAEL H. THALER
PRIMARY EXAMINER
GROUP 3300